

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>UNITED STATES OF AMERICA</b>	<b>:</b>	<b>CRIMINAL NO.</b>
<b>v.</b>	<b>:</b>	<b>DATE FILED:</b>
<b>WILLIAM A. MERLINO</b>	<b>:</b>	<b>VIOLATION:</b>
	<b>:</b>	<b>21 U.S.C. §§ 331(a), 352(a),</b>
	<b>:</b>	<b>333(a)(2) (introduction of misbranded</b>
	<b>:</b>	<b>drugs into interstate commerce – 1 count)</b>
	<b>:</b>	<b>Notice of forfeiture</b>

**INDICTMENT**

**COUNT ONE**

**THE GRAND JURY CHARGES THAT:**

At all times material to this indictment:

**Introduction**

1. Defendant WILLIAM A. MERLINO was a retired physician, licensed to practice medicine in the State of New Jersey.
2. The United States Food and Drug Administration (“FDA”) was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug and Cosmetic Act (“FDCA”). Among the purposes of the FDCA was to assure that human drugs are safe, effective, and bear labeling containing only true and accurate information. The FDA’s responsibilities under the FDCA included regulating the manufacture, labeling and distribution of all drugs shipped or received in interstate commerce.
3. Under the FDCA, “drugs” were defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man, 21 U.S.C. § 321(g)(1)(B);

articles intended to affect the structure or any function of the body of man, 21 U.S.C. § 321(g)(1)(C); or articles intended for use as components of other drugs, 21 U.S.C. § 321(g)(1)(D). Whether a product is considered to be a drug depended on its intended use. Intended use is determined by the objective intent of the person responsible for labeling the drugs and may be shown by such person's expressions or may be shown by the circumstances surrounding the distribution of the product. The objective intent may be shown, for example, by labeling claims, advertising matter, or by oral or written statements by such persons or their representatives. 21 C.F.R. § 201.128.

4. The term "label" was defined as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was broader, and included all labels and other written, printed or graphic matter upon any article, including drugs, or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

5. Under the FDCA, it was a prohibited act to introduce or deliver for introduction, or to cause the introduction or delivery for introduction, into interstate commerce a drug that was misbranded. 21 U.S.C. § 331(a).

6. A drug was misbranded if, among other things, its labeling was false or misleading in any particular. 21 U.S.C. 352(a).

7. The FDCA provided that before a new drug can be shipped in interstate commerce, its manufacturer must obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans). 21 U.S.C. §§ 355(b),(j),(i). To receive

approval to market a drug, the manufacturer must submit information showing that the new drug is safe and effective for its intended use. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

### **The Drug**

8. 2,4-Dinitrophenol (“DNP”) was an industrial chemical with various commercial uses, including in herbicides, dyes, wood preservatives, photographic developers, and explosives.

9. In the 1930’s, before Congress passed laws requiring drugs to be proven safe before they were marketed, DNP was used extensively as an over-the-counter weight loss drug. As a weight loss product, DNP caused serious adverse events, including dehydration, cataracts, liver damage, and death. As more side effects were reported, FDA issued a statement that DNP was “extremely dangerous and not fit for human consumption.”

10. FDA has never approved a drug that contains DNP.

11. Despite the known dangers and its unapproved status, DNP continues to be distributed illegally. It is particularly popular with bodybuilders and athletes because of its ability to affect the body and rapidly lose body fat.

### **The Defendant’s Business**

12. From at least in or about November 2017, to in or about March 2019, defendant WILLIAM A. MERLINO operated a business to encapsulate, package, label and distribute DNP from his residence in New Jersey.

13. Defendant WILLIAM A. MERLINO used the screen name “simcare” on eBay to market and sell DNP as a weight loss drug and “fat burner” despite his knowledge that

DNP was not approved by the FDA as a human drug. Defendant MERLINO offered the DNP for sale as powder, or, for an additional charge, as encapsulated pills.

14. On other occasions, defendant WILLIAM A. MERLINO purported to sell DNP for agricultural use, but would also advertise the historical use and dosages of DNP as a weight loss aid.

15. Defendant WILLIAM A. MERLINO advertised through Twitter, stating that DNP was for sale on eBay “for weight loss. It is not legal in US so listed as fertilizer on eBay. #Diet #weightloss.”

16. When eBay removed all listings of DNP for sale, defendant WILLIAM A. MERLINO conducted transactions through his email address simcare@gmail.com and his website [www.fortissupply.com](http://www.fortissupply.com). Defendant MERLINO labeled his drugs “Not For Human Consumption” or as fertilizer, despite knowing and intending that they were to be used for weight loss. He did this to avoid regulatory scrutiny because he knew that it was illegal to distribute DNP in the United States for a drug use.

17. Defendant WILLIAM A. MERLINO distributed misbranded drugs containing DNP to customers and received thousands of dollars of cash in return.

18. Defendant WILLIAM A. MERLINO shipped misbranded drugs containing DNP throughout the United States and to foreign countries, including the United Kingdom and Canada.

### **The Charge**

19. From in or about November 2017, to in or about March 2019, in the Eastern District of Pennsylvania and elsewhere, defendant

**WILLIAM A. MERLINO,**

with the intent to defraud and mislead, introduced into interstate commerce, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce from the State of New Jersey to the Commonwealth of Pennsylvania 2,4-Dinitrophenol (“DNP”), a drug that was misbranded for having labeling that was false and misleading in any particular, specifically, by stating that it was fertilizer and/or “not for human consumption” when he knew and intended that the DNP be used and consumed as a human drug.

All in violation of Title 21, United States Code, Sections 331(a), 352(a) and 333(a)(2).

**NOTICE OF FORFEITURE**

**THE GRAND JURY FURTHER CHARGES THAT:**

1. As a result of the violations of Title 21, United States Code, Sections 331(a), 352(a), and 333(a)(2) set forth in this indictment, defendant

**WILLIAM A. MERLINO**

shall forfeit to the United States of America, any quantities of 2,4-Dinitrophenol (“DNP”) which, from in or about November 2017 to in or about March 2019, were misbranded when introduced into interstate commerce and may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

- (a) cannot be located upon the exercise of due diligence;
- (b) has been transferred or sold to, or deposited with, a third party;
- (c) has been placed beyond the jurisdiction of the Court;
- (d) has been substantially diminished in value; or
- (e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is, \$54,800.

